

Journal of Contemporary Health Law & Policy (1985-2015)

Volume 1 | Issue 1

Article 6

1985

Legal Implications and Law Making in Bioethics and Experimental Medicine

Russell Scott

Follow this and additional works at: <https://scholarship.law.edu/jchlp>

Recommended Citation

Russell Scott, *Legal Implications and Law Making in Bioethics and Experimental Medicine*, 1 J. Contemp. Health L. & Pol'y 47 (1985).

Available at: <https://scholarship.law.edu/jchlp/vol1/iss1/6>

This Article is brought to you for free and open access by CUA Law Scholarship Repository. It has been accepted for inclusion in Journal of Contemporary Health Law & Policy (1985-2015) by an authorized editor of CUA Law Scholarship Repository. For more information, please contact edinger@law.edu.

LEGAL IMPLICATIONS AND LAW MAKING IN BIOETHICS AND EXPERIMENTAL MEDICINE

*Russell Scott**

I. BIOETHICS

In 1958, looking back at his famous novel, Aldous Huxley wrote:

In 1931, when *Brave New World* was being written, I was convinced that there was still plenty of time Twenty-seven years later . . . I feel a good deal less optimistic The prophesies made in 1931 are coming true much sooner than I thought they would And why has the nightmare, which I had projected into the seventh century A.F. [after Ford] made so swift an advance in our direction? The answer to these questions must begin where the life of even the most highly civilized society has its beginnings — on the level of biology.¹

What would Huxley say today, in 1984, almost twenty-eight years after his 1958 doubts? Would the birth of healthy "test tube" quadruplets in Melbourne last January,² following the birth two months earlier of a normal baby to a woman who had not only been through menopause but had be-

* Mr. Scott is Deputy Chairman of The Law Reform Commission in New South Wales, Australia, and Chairman of the Advisory Committee on Human Artificial Insemination. A dynamic force in the Law Reform Movement of "The New Biology," he is the author of the highly respected book entitled, *The Body As Property*, published in not only Australia, but in Britain, France, and the United States. A graduate of The University of Sydney and The London School of Economics and Political Science, Mr. Scott became subsequently enrolled as a Solicitor and as a Barrister of the Supreme Court of New South Wales as well as a Solicitor of the Supreme Court of England. From 1959 to 1978, he practiced as a partner with Dawson & Waldron, in Sydney. In 1981 he became a member of the Committee of the National Health and Medical Research Council to develop a National Code of Practice for Cadaver Tissue Donations and in 1982 became a member of the Committee of the National Health and Medical Research Council to develop a National Code of Practice for Cadaver Tissue Donations and in 1982 became a member of the Committee of the Council to develop National Guidelines for Medical Research and Human Experimentation—with particular reference to *in vitro* fertilization.

Due to the impossibility of obtaining access to several Australian newspaper citations, several of the footnotes may vary slightly from The Harvard Uniform System of Citation—Ed.

1. A. HUXLEY, *BRAVE NEW WORLD REVISITED* 11-15 (1959).

2. Miner, *In-vitro Quadruplets Take a Bow. . . and Dad is on Cloud Nine*, Sydney Morning Herald, Jan. 7, 1984, at 3, col. 2.

come pregnant by the implantation in her womb of a laboratory-fertilized embryo made from an ovum donated by another woman,³ have caused him to re-cast the following words which appear in the same pages?

Babies in bottles and the centralized control of reproduction are not perhaps impossible; but it is quite clear that for a long time to come we shall remain a viviparous species breeding at random. For practical purposes genetic standardization may be ruled out.⁴

So great has been the rate of medical and scientific advance in human biology and physiology since mid-century that a new discipline, a new field of intellectual concern, now flourishes under the name Bioethics (from the Greek *bios* (life) and *ethike* (ethics). Bioethics involves the study of human conduct in health care and the practice of medicine, with particular attention to the beginning of life, the end of life, and the impact of modern medical and scientific advances upon basic human values.⁵ Bioethics tends to be an interdisciplinary affair which requires the attention not just of medical men and scientists but philosophers, lawyers, moralists, theologians and social scientists, to name a few.

Developments such as *in vitro* fertilization, human artificial insemination, the freezing and storage of human gametes and embryos for later resuscitation and use, the concept of brain death, the maintenance of life by artificial means in the grossly defective aged and newborn, the so-called "right to die," surgery upon embryos *in utero*, the decision by the United States Supreme Court in 1980 to authorize a patent for a new form of man-made living organism,⁶ and the breeding by genetic engineering of an entirely new species of animal, namely a "giant" mouse,⁷ demand interdisciplinary study and attention.

A penetrating comment was recently made by a member of the Monash University Center for Human Bioethics:

Ethical inquiry is important to us when we are unsure of the direction in which we are heading. Like philosophy, it thrives on self-doubt Today, new practices in the biomedical sciences are

3. *Baby a World First for Melbourne in vitro Team*, Sydney Morning Herald, Jan. 14, 1984, at 3, col. 1.

4. *Supra* note 1, at 13.

5. See generally, 1 *ENCYCLOPEDIA OF BIOETHICS* (W.T. Reich, ed. 1978).

6. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). See Smith, *The Promise of Abundant Life: Patenting a Magnificent Obsession*, 8 J. CONTEMP. L. 85 (1982).

7. B. MORRIS, *UNNATURAL SELECTION AND THE DESTINY OF HUMANITY* (1984). For an analysis of this paper see *Robinson, . . . and What We May Become!*, The Australian, Jan. 26, 1984, at 1, col. 1.

challenging old thoughts: New medicine calls us all in doubt.⁸

The author was writing of recent advances in the biomedical sciences that now allow us to intervene in, and on occasions control, the processes of life and death; examples, which I intend to consider in more detail, include *in vitro* fertilization, artificial insemination, and the concept of brain death. "It is not surprising, then, that in the wake of these revolutionary developments bioethics is flourishing."⁹

What do we mean when we use the word "ethics?" The answer to that question would require more space than is available in this paper. However, I believe that I should give some indication of the sense in which I use the word. I am content to accept the approach of the American moral theologian Thomas J. O'Donnell, who wrote in 1976 that ethics is a study or investigation into both the goodness and evil of human actions in light of natural reason. He continued by contrasting ethics with moral theology which he observed, "on the other hand, investigates the morality of human actions against the background of man's supernatural life and destiny, and with the added assistance of divine revelation."¹⁰ O'Donnell doubts whether "medical ethics" should be a distinct field, different from ethics generally. He believes that ethics lives "at the heart of man His ethic is his concern for the moral goodness of what he does."¹¹ The idea that ethics should contain something more than individual personal opinion and, on the other hand, something more than religious propositions is appealing. Kuhse, in her analysis of the ethics of *in vitro* fertilization adopts a notion of ethics similar to that of O'Donnell, although she makes no reference to his work. She builds her conclusions in part on the views of 18th and 19th century thinkers such as Hume and Kant.¹²

In our present changing society, questions are continually asked about the most profound ethical dilemmas, for example, the sanctity of life, as typified by the debates on abortion, euthanasia, and artificial conception. Yet, it is not long since some medical men believed that the only fit contents for a university course on medical ethics were manners and behavior—a kind of obsession with questions about the pecking order within the profession. Direct evidence of this was given to the Australian Law Reform Commission in 1977. Indeed, at that Commission we became so concerned at the absence of instruction in ethics in the medical faculties of some Australian universities

8. Kuhse, *An Ethical Approach to IVF and ET: What Ethics is All About*, in *TEST-TUBE BABIES* 22 (W. Walters & P. Singer, eds. 1982).

9. *Id.* at 23.

10. T. O'DONNELL, *MEDICINE AND CHRISTIAN MORALITY* 6 (1976).

11. *Id.* at 4.

12. *Supra* note 8, at 28.

that we wrote an official appeal to the deans of medical faculties throughout Australia. In our 1977 report, *Human Tissue Transplants*, we invited all such faculties to consider the adequacy of their curricula.¹³

For my purposes "ethics," in the sense of a set of rules for behavior, is a principles of general application whereby the goodness or badness of human conduct may be judged by reference to reason and consistency. Ethics therefore is not theology, but it does involve some supporting theism. However, ethics and morality are intertwined.

Examples of Current Bioethical Problems

I now propose to examine two unprecedented clinical relationships, both capable of being labeled biomedical and experimental, both rapidly becoming commonplace in medical practice, both virtually unheard of until twenty years ago or less, and both abounding with ethical questions. The first concerns the condition known as brain death, and its relationship with the unconscious patient in intensive care, and includes the plight of the aged as well as the newborn whose bodies can function only with artificial support. The second concerns the patient who seeks to become pregnant by artificial procedures (artificial insemination (AI) or *in vitro* fertilization (IVF) and embryo transfer (ET)).

Unconscious Patients and the Helpless Aged and Newborn

In October 1977 Carol Wilkinson, a woman of twenty, was violently attacked while walking to work in Bradford, England. She was battered about the head with a stone, and was unconscious when admitted to the hospital where she was promptly connected to a ventilator. After three days of monitoring and testing, there was no detectable brain function. According to the subsequent Law Report, "the medical team in whose charge she was, after a number of tests, concluded that her brain had ceased to function and that accordingly the ventilator was operating on a lifeless body. The life support machine was disconnected and all bodily functions ceased shortly afterwards." There was no mention of the involvement of the family of the patient, or anybody else, in the diagnosis of brain death or the discontinuance of the machine. Carol Wilkinson's assailant was subsequently arrested, charged with murder, and convicted. He appealed to the Court of Criminal Appeal, asserting that he was not guilty of murder, in that the doctors of the medical team, by switching off the ventilator, were responsible for her homicide. This argument was rejected, and the appeal dismissed.¹⁴ A similar

13. Commission Report No. 7, 7 Aust. L. Ref. Comm. 12 (1977).

14. [1981] R. v. Steel, 1 All E.R. 422.

case was heard by the same court at the same time with the same result.¹⁵

Examples can be given from a variety of countries of doctors who have not only been involved in litigation but have run afoul of the law by resorting to the brain death concept. Most of these cases occurred in the late 1960's or early 1970's. In Japan, Europe, and the United States eminent surgeons were embroiled in both criminal and civil legal proceedings because of the lack of clear recognition by the law that death may be diagnosed by reference to irreversible cessation of brain function.¹⁶

Turning to current practice in Australia, the concept of brain death is well accepted, understood, and applied in intensive care. It is now recognized by statute as a lawful means of diagnosing death in almost all states and territories.¹⁷ The specialist in charge of the intensive care unit at a leading New South Wales teaching hospital has informed me that that hospital commonly uses the criteria for brain death promulgated unanimously by the British Royal Colleges of Medicine in 1976, unanimously reiterated by them in 1979,¹⁸ and adopted by Australian Royal Medical Colleges. When a determination has been made that a patient has suffered brain death it follows that support machinery will be discontinued. The New South Wales hospital to which I referred believes that the determination of death is entirely a medical matter and that the decision to disconnect life-support machinery is also a medical matter. At the same time, the hospital firmly believes that the family of an unconscious patient in intensive care should be brought into the case as early as possible, given liberal access to the patient, and kept advised of his progress at least once a day. It has found from experience that this kind of involvement makes it less arduous to tell them that brain death has occurred. The hospital makes a point of informing relatives of the occurrence of death (i.e., brain death) and normally disconnects life-support machinery after the information has been passed on. It has rarely had cases where relatives have attempted to insist that the life-support machinery be continued. In such cases the hospital insists on exercising its own right to

15. [1981] R. v. Malcherek, 1 All E.R. 422.

16. *Transplant in Question*, The Times, Sept. 4, 1970, at 4, col. 1. This news account reports on the supreme prosecutor's office in Tokyo's ruling that insufficient evidence existed to indict Professor Juro Wada of the Sapporo Medical College on a charge of "homicide by misadventure" in connection with Japan's first and only heart transplant operation in 1968.

For reference to a similar Swedish case, see *UPDATING LIFE AND DEATH: ESSAYS IN ETHICS AND MEDICINE* 21 (D.R. Cutler, ed. 1968).

17. The exceptions are Tasmania and Western Australia.

Although it was reported that Western Australia intended to enact legislation recognizing brain death, it has yet to be passed. See Simmonds, *WA Defines 'Death' to Protect Doctors*, The Australian, Sept. 29, 1983, at 3, col. 1.

18. *Diagnosis of Death*, THE LANCET, Feb. 3, 1979, at 261.

withdraw the life-support. The hospital has found that continuation of life-support machinery to a patient in whom brain death has been diagnosed has a disruptive and adverse effect upon the nursing and medical staffs generally.

Initial decisions to connect a patient to life-support machinery are normally a much simpler matter than disconnection. Many patients are brought into a hospital unconscious and connected to ventilators almost as a routine matter. Occasionally the question of whether to connect a person to a ventilator will be more complicated. An example of this arose in the same New South Wales hospital and involved a ninety year old lady who suffered from a severe respiratory disease who obviously had only a very short time to live.¹⁹ The decision in such a case will involve many factors including respect for the dignity and suffering of the patient, the amount of equipment available in the hospital as well as the claims of other patients.

The problems presented by the brain dead patient can be less taxing than those presented by other unconscious patients whose comatose condition does not amount to brain death. Probably the best known and most troublesome case of this kind is that of Karen Quinlan who has been in a coma in the United States since April, 1975, when she was twenty-one years of age. Karen Quinlan retains some residual function of the brain stem. Accordingly she has not suffered brain death although it appears that there is no prospect that she can ever regain consciousness. None of the medical experts involved in the legal proceedings concerning her condition held out any hope that she could ever recover.²⁰

Intractable difficulties can occur when artificial life support by modern machinery and technology is supplied to the coma patient who is not brain dead, the helpless aged patient who is dying, the hopelessly defective newborn child, and other sick or dying human beings whose existence may be an intolerable burden to themselves, their families, and the community. Except for the appearance in most Australian jurisdictions of a statutory recognition of brain death, the present Australian law can offer little comfort or help in solving these problems. All that it is able to do is to produce the criminal law of homicide as a general inhibition to those working in the field. Numerous other countries are in the same position. The laws of the past were not designed for such circumstances. The law is often a crude instrument and it certainly seems to be so in a case where a family or a medical practitioner is forced to take defensive measures against the laws of homicide. Speaking generally, a person commits the crime of murder if he or she intends to kill

19. Information supplied by Dr. D. Tabrett, Head of Intensive Care, Sydney Hospital, Sydney, Australia, July 23, 1981.

20. See Colleser, *Death, Dying and the Law: A Prosecutorial View of the Quinlan Case*, 30 RUTGERS L. REV. 304 (1977).

another or to inflict grievous bodily harm, and the death of the other person results. The essential ingredient is the intention to kill. If death is intended, the law as written will take no account of the motive no matter how humane.²¹ The crime of murder may in certain circumstances be reduced to some lesser offense if the act was not intended to inflict grievous bodily harm or was due to negligence. But an act intended deliberately to shorten the life of a person remains under the law a homicide and the consent of the deceased or his family will not alter it. Of course, those who administer the initiation of criminal procedures may decide not to take action in some cases but there can be no certainty of restraint in every case.

It is therefore not surprising that a great deal of secrecy pervades these areas of modern medical practice. We must prescribe better procedures. With our aging population decision-making about the continuation or cessation of treatment for patients of the kind described above is now a daily occurrence.

Some Bioethical and Legal Solutions

Professor Paul Ramsey, the American philosopher and moral theologian, has suggested that the most useful result would come from an honest decision by all the medical men and others involved, as to the patient's prospects of recovery to a form of living acceptable to the community.²² If their best conclusion is that no such prospect exists and that continued treatment aimed at producing a cure is nothing but prolongation of dying then the use of "heroic" or even "standard" measures of curative treatment is no longer indicated. Ramsey suggests that there must be a power to bring to an end treatment which is curative in nature—that is, designed to restore a patient to reasonable health—but has no hope of achieving that end.²³ This does not mean that other treatment aimed, for example, at making a dying patient comfortable, should also be discontinued. Maybe it should or maybe it should not. It will depend ultimately on the facts of the case.²⁴

Both the law and the community should recognize some objective standards of treatment to prevent hospitals or doctors from being forced into procedures based on fear of legal consequences. Conversely, the community needs protection and security against excessive power on the part of the medical profession to decide survival or death without restraint. Ramsey suggests that in every case a decision should be made at a proper time

21. C. HOWARD, *AUSTRALIAN CRIMINAL LAW* 36 (3d ed. 1977).

22. Ramsey, *Prolonged Dying: Not Medically Indicated*, *HASTINGS CENTER REP.* 14 (Feb. 1976).

23. *Id.*

24. *Id.*

whether further treatment aimed at a cure is "indicated" or "not indicated." If a patient is regarded as dying, the nature of the treatment should then change.²⁵

A revulsion against the maintenance of life in extreme cases has spread in the wake of the *Quinlan* decision and since the Californian lead in 1976, a number of "natural death" acts have appeared in the United States.²⁶ Such legislation has been under consideration in two Australian states, South Australia and Victoria. In the United States, allied laws have been introduced in New Mexico and Arkansas where it is now lawful to withdraw artificial life support from terminally ill children with the consent of parents and a court, provided the child does not object.²⁷

The object of this kind of law is to prevent the direct exercise of dominion over a helpless body in a way that many see as inhuman and degrading. One case was reported to a medical journal by an American doctor in the following words:

It is true that death is rarely dignified but it is also undignified to die with a urethral Foley catheter connected to a drainage bag, a continuous (intravenous) IV running, a colostomy surrounded with dressings, and irrigation tubes stuck into an abscess cavity around the colostomy, a CVP line, a moisturized oral endotracheal tube attached to a Bennett respirator taped to the face, an oral airway, a feeding nasogastric tube also taped to the face, and all four extremities restrained. This is the way a friend and colleague of mine died. When I went in to greet him two days before he died I could hardly get to the bed because of all the machinery around him The friend, of course, couldn't speak, and when he lifted his hand, it was checked by a strap. Is it necessary to do this to a human being so his family won't feel guilty about wishing him to have peace at last?²⁸

25. *Id.*

26. For example in: ARK. STAT. ANN. §§ 82-3801 through 3803 (1983 supp.); CAL. [HEALTH & SAFETY] CODE §§ 7185-7195 (1984 Supp.); IDAHO CODE §§ 9-4501 through 4508 (1984 Supp.); NEV. REV. STAT. § 449.540-600 (1977); N.M. STAT. ANN. §§ 24-7-1 through 24-7-10 (1984); N.C. GEN. STAT. §§ 90-320 through 90-323 (1981); TEX. CODE ANN. § 4590(h) (Vernon, 1984 Supp.).

27. See, e.g., ARK. STAT. ANN. §§ 82-2801-2804 (Supp. 1978); N. MEX. STAT. ANN. §§ 24-7-1-11 (1978).

See generally, B. SALES, D. POWELL, R. VANDUIZEND ET AL. *DISABLED PERSONS AND THE LAW: STATE LEGISLATIVE ISSUES* (1982).

28. Letter to Medical Economics Mag., quoted in Horn, *Death-with-Dignity Laws in America*, The Nat'l Times, Oct. 3 - Oct. 8, 1977, at 36, col. 4.

Infertility and Artificial Conception

In Australia at present the practices of human artificial insemination (AI) and *in vitro* fertilization (IVF) and embryo transfer (ET), are carried out as means of dealing with infertility in marriage. There is no doubt that artificial insemination of married women by donor sperm with the consent of the infertile husband (AID) is a widespread practice which is growing.²⁹ One of the immediate reasons for these activities is the acute shortage of children for adoption. As for IVF, this highly skilled work has been usually, but not exclusively, employed to assist married couples where the wife has problems with her fallopian tubes but both parties are otherwise normal as far as reproductive capacity is concerned.³⁰ In 1977, the Australian Law Reform Commission drew public attention to AID, IVF, and ET and the possibility of the birth of children by these processes.³¹ The Commission recommended that the Australian Government should give early consideration to the social, moral and legal questions involved.

Until 1982, there was little government activity but a great deal of public debate. Issues have now crystallized, particularly since the development of techniques whereby a woman will produce a number of eggs during her monthly cycle (superovulation), and the development in Australia in April 1981 of freezing techniques whereby reproductive tissues, including fertilized eggs, can be stored for later thawing and implantation.³² This capacity

29. See generally, *ARTIFICIAL INSEMINATION BY DONOR*, (C. Wood, ed. 1980); Smith, *Through a Test-Tube Darkly: Artificial Insemination and the Law*, 67 MICH. L. REV. 127 (1968).

30. *Supra* note 8.

31. *Supra* note 13.

Chapter Four of AUST. L. REF. COMM. REP. at 7 discusses some of the implications of IVF, ET, AI, and other medical activities concerned with human reproductive tissues.

32. A reading of press reports in Australia, Britain, and the United States in the months following the announcement in Australia in April, 1981, that a Melbourne IVF clinic was holding over twelve surplus fertilized human eggs in cold storage will support this conclusion. See, for example, the attention given to *in vitro* fertilization in January and February, 1982, by *The Times* (of London), *The Sydney Morning Herald*, *TIME MAGAZINE*, *NEWSWEEK* and *NATURE*.

See also, Harrington, *For and Against: The Essence of the Arguments as They Appeared in the Press*, in *TEST-TUBE BABIES*, *supra* note 8.

In March, 1978, the Chief Rabbi of the British Commonwealth, Dr. J. Jacobovits, publicly stated in Sydney, Australia, "[W]e would not like to see parents replaced by machines or computers or test tubes," *The Age* (Melbourne), Mar. 10, 1975. Six months later, Lord Soper, the well-known English Methodist clergyman, said in Sidney, "[A]rtificial insemination fulfils a woman's role in bringing another human being into the world. I cannot see any reason why a woman should not have a test-tube babe." *The Australian*, Sept. 6, 1978. On August 24, 1982, it was reported that "[T]he Catholic bishops of Victoria have told a State Government inquiry that *in vitro* fertilization is unacceptable." The first ground of unacceptability advanced by the bishops was that "no process [is] morally or socially acceptable nor condonable

to freeze and store tissues perhaps indefinitely, and the addition of two previously unknown characters to the IVF (and AI) *dramatis personae*, namely, the ovum donor and the surrogate mother, have precipitated unprecedented questions and issues. In this article because of space restrictions, it will be possible to do little more than list the most significant.

1. Frozen, stored reproductive tissues: The technology now exists for freezing, storing, thawing, and using not only human sperm (and, it is believed, eggs) but fertilized eggs or embryos. This has long been seen as an important aid to successful IVF and ET.³³ Accounts of the birth of the world's second test tube baby in Calcutta, India, in October 1978 claim that the (IVF) fertilized egg had been held frozen for fifty-three days before implantation. The achievement of pregnancy by the implantation of previously-frozen IVF embryos in Melbourne is well-known.³⁴ To some people this technology may suggest possibilities of selective breeding, population control, and ownership of human beings. Therefore consideration must be given to not only the implications of the collection and storage of these tissues but also of their disposition, discard, and destruction, as well as ownership, commerce, experimentation, and the conduct of tissue banks.³⁵ I emphasize that I am not here referring to future events. At least one commercial organization in the United States has for some time engaged in international trade in human semen; and mail-order do-it-yourself artificial insemination kits have long been available in the United States.³⁶

Apart from the central legal considerations of ownership and property rights in the tissues,³⁷ there are more specific legal questions. What effect will the tissue banks and IVF have upon the law of wills? What effect can be given to a testamentary gift "to my children" by a man who has banked sperm or a couple who have banked an embryo? There is no physical reason why the banked embryo could not be implanted in and borne by a relative of the couple, their own granddaughter for that matter, or by a friend or a purchaser. Already, a woman has given birth to her husband's child more

by the law which involve[s] destroying, discarding or freezing human embryos. . . ." *The Age* (Melbourne), August 24, 1982.

33. Edwards & Steptoe, *The Relevance of the Frozen Storage of Human Embryos* in *THE FREEZING OF MAMMALIAN EMBRYOS* at 235 (52 CIBA Foundation symposium, New Series 1977). See also *supra* note 8, at 9, 10.

34. In relation to the Calcutta birth, see *Sydney Morning Herald*, Oct. 10, 1978, at 8-10.

35. *Supra* notes 13 and 31; *infra* note 50.

36. Information supplied by letter to the author from the Director, Institute of Population Studies, University of Exeter, England, in January 1980.

37. Scott, *Legal Implications of In Vitro Fertilization and Embryo Transfer*, at 24-26, AN-SAAS Congress, Sydney, May 11, 1982.

than a year after his death, by using his frozen sperm.³⁸ The facts of life no longer accord with a historic tenet of the law, namely, that the child of a woman cannot be born after (i.e., any appreciable length of time after) her death and that a man's children cannot be born more than nine months after his death. What effect will this new technology have upon the Rule Against Perpetuities in its classic form?

Let it not be thought that these are remote seminar points unlikely to impinge upon real life. The Supreme Court of New South Wales has already ruled that evidence relating to the cryo-banking of reproductive tissues must be supplied when the court is asked to sanction the distribution of an estate to "the children" of a consenting life tenant who is a woman beyond the normal age of child-bearing.³⁹

2. Surrogate motherhood: Surrogate motherhood by means of AI is well established in the United States where expert legal and medical practitioners have appeared in recent years specializing in its arrangement and implementation.⁴⁰ A "surrogate mother" is a "substitute mother," that is a woman who agrees to bear a child for somebody else. In a typical situation a married couple will make an arrangement with the surrogate under which she will be artificially inseminated with the husband's sperm. She may or may not be paid. Surrogate motherhood has a respectable lineage, whatever its future may be. Two curious biblical examples are described in the Book of Genesis, the second being of particular interest because Rachel, the wife of Jacob required the surrogate Bilhah to "bear upon my knees, that I may also have children by her."⁴¹

Surrogate motherhood contracts raise important legal and social issues. If the law were to make them effective it would be necessary to assume direct control of personal behavior and to assert dominion over the body of the surrogate. Such contracts prescribe conditions under which a child is to be conceived, born, and transferred. Major questions of public policy are involved. Litigation has already taken place in England and in the United States following disputes between parties to such contracts.⁴²

Moreover, surrogate motherhood is not limited to people involved with the practice of AI. In Australia, medical practitioners have recently applied

38. *Love . . . 18 Months Later*, Sydney Morning Herald, July 12, 1977, at 4.

39. *Bullas v. Public Trustee*, 1 N.S.W.L.R. 641 (1981).

40. N.P. KEANE, D.L. BREO, *THE SURROGATE MOTHER* (1981); Seligman & Curry, *Pregnancy by Proxy*, NEWSWEEK, July 7, 1980, at 49.

See Smith, *The Perils and Peregrinations of Surrogate Mothers*, 1 INT'L J. L & MED. 325 (1982).

41. GENESIS 16, 30:3 (King James).

42. *A. v. C.* (1978); 8 FAM. LAW 170; *The Baby Born of Surrogate Mother*, Sydney Morn-

a new expression to describe surrogate motherhood achieved by sexual intercourse between the surrogate and a married man with his wife's consent. The expression is NID (Natural Insemination Donor).⁴³ Wide publicity was given in New South Wales in April and September, 1982 to a case of this kind.⁴⁴ The Department of Youth and Community Services, which controls the adoption of children in that State, has received since 1982 a number of formal written applications by members of the public requesting prior approval to surrogate motherhood contracts and the ultimate adoption of the children conceived.⁴⁵

With IVF an additional difficult legal and social question arises. Will a test tube baby from a surrogate mother be the child of the surrogate, or of the donor of the egg, or of both? There has been a great deal of legal surmise on this question.⁴⁶ Some writers suggest that the mere donation of the genetic material is insufficient to sustain the donor's claim to motherhood and that the physical connection of the embryo to the surrogate's body introduces new factors. On the other hand, the embryo itself is a genetic stranger to the surrogate. If the child is to be regarded as having two mothers what should the law say, for example, in relation to maternal rights and duties, and inheritance of property? The Australian national ethical guidelines on *in vitro* fertilization of August 1982⁴⁷ referred to surrogate motherhood but refrained from prescribing ethical guidelines because no IVF child had been born from a surrogate mother and insufficient emergence of community attitudes had taken place.⁴⁸

3. Ovum donation: On the face of it, ovum donation is similar to surro-

ing Herald, April 25, 1981, at 3; *Surrogate Mother Can Keep Baby, Judge Rules*, Sydney Morning Herald, June 6, 1981, at 9.

See Smith & Iraola, *Sexuality, Privacy and the New Biology*, 67 MARQUETTE L. REV. 63 (1984).

43. Oral information given to The Advisory Committee on Human Artificial Insemination (New South Wales) in 1982 by the head of the infertility clinic of a Sydney Public Hospital.

44. Stubbs, *Couple in Last-Ditch Bid to Become Parents*, The Northern Star (Lismore, New South Wales), April 19, 1982, at 2, col. 1; Stubbs, *Surrogate Mother for Ballina Couple is Now Pregnant*, The Northern Star (Lismore, New South Wales), Sept. 16, 1982, at 2, col. 1.

45. Information supplied orally to the author in 1982 by The Department to The Advisory Committee on Human Artificial Insemination.

46. Sappideen, *Life After Death--Sperm Banks, Wills and Perpetuities*, 53 AUST. L. J. 311, 319 (1981); Stone, *English Law in Relation to A.I.D. and Embryo Transfer* in 17 CIBA FOUNDATION SYMPOSIUM (New Series 1973) at 75; Rassaby, *Surrogate Motherhood: The Position and Problems of Substitutes*, in TEST-TUBE BABIES, *supra* note 8, at 99, 100.

47. For a description of these guidelines, see text under heading Australia and *infra* notes 80, 81, and 82.

48. For discussion of the issues see Rassaby, *supra* note 46; Walters, *Human In Vitro Fertilization: A Review of the Ethical Literature*, HASTINGS CENTER REP. 23, (Aug. 1979).

gate motherhood. The procedure envisages the gift of an ovum to an infertile wife, its fertilization *in vitro* with the husband's sperm, and its subsequent transfer to the uterus of the wife. Analogy is more naturally made, however, with artificial insemination using donor sperm (AID) than with surrogate motherhood.⁴⁹ The intention of all parties is that the child will be borne by and retained by the recipient of the egg. While there are obviously legal questions to be answered (for example, the question of motherhood), they are not of the same seriousness as those posed by surrogate motherhood.

The Australian national ethical guidelines on *in vitro* fertilization of August 1982 prescribed conditions under which ovum donation for IVF may be ethically practiced.⁵⁰ In contrast, a committee established by the Victorian Government in 1982 to examine aspects of *in vitro* fertilization recommended in an interim report that ovum donation for IVF should not be permitted. Furthermore, it believed that the practice should be confined to the implantation in married women of gametes obtained only from the recipient woman and her husband.⁵¹ The final report of the same Committee, in August 1983, reversed these recommendations and advised the Victorian Government to establish statutory supervision over the donation of gametes for the purpose of artificial conception. The recommendations extend to the establishment of detailed registers by hospitals and the state, as well as the creation of a network of offenses. It is expected that a bill will be introduced into the Victorian Parliament to implement this report within a matter of months.⁵²

Events have, as usual, moved ahead of the law. The first test tube baby born following the implantation of an IVF embryo made in the laboratory from a donor egg, occurred in Melbourne in November 1983.⁵³

4. The moral status of the embryo: This expression, which refers to the status to be accorded to a fertilized egg (embryo), is the most significant philosophical issue raised by IVF. There are those who assert that from the moment of fertilization an egg must be regarded as a human person and should be given legal protection as such.⁵⁴ Others, including philosophers,

49. Walters, *supra* note 48, at 31.

50. N.H. & M.R.C. Statement on Human Experimentation and Supplementary Notes, at Supplementary Note 4, para. (3). See also *supra*, note 47.

51. Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Victoria, Australia, Interim Report at 26, 27 (Sept. 1982).

52. Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, REPORT ON DONOR GAMETES IN IVF, Victoria, Australia, (Aug. 1983).

53. *Supra* note 2.

54. Johnstone, Kuhse, & Singer, *The Moral Status of the Embryo: Two Viewpoints*, in TEST-TUBE BABIES, *supra* note 8, at 49; Harrington, *supra* note 32; Lappe, *Ethics at The*

moral theologians, and experts closely connected with the practice of IVF, do not agree that the fertilized egg should be treated as a person from that moment.⁵⁵ Public debate on the issue has, on occasions, been acrimonious, and it may well prove impossible to achieve a total community consensus. If a conclusion can be drawn from the lack of legal prohibition of IVF in Western nations and the growth of the practice since 1978, it could indicate that those who take the fundamentalist or deontological view described first above are in a minority.⁵⁶

The following questions, issues, and assertions have also been widely discussed: a) Does IVF involve unjustified cost, and misallocation of resources?⁵⁷ b) Is IVF unnatural?⁵⁸ c) Should access to IVF be legally limited, for example, to married couples?⁵⁹ d) IVF may involve unacceptable risk to the mind or body of the resulting child.⁶⁰ (The intensity of debate on this question has decreased with the birth of normal IVF children. Long-term effects are, for obvious reasons, still unknown.) e) Informed consent should be given by all participants in IVF procedures.⁶¹ f) Is infertility a condition that should be treated medically?⁶² g) IVF may lead to genetic engineering, cloning, the birth of chimeras, and to ectogenesis.⁶³ h) IVF should be stopped for fear of what scientists may do next.⁶⁴

II. EXPERIMENTAL MEDICINE

Despite its success in producing the births of many healthy babies, IVF is,

Center of Life: Protecting Valuable Subjects, HASTINGS CENTER REP. 11 (Oct. 1978); Walters, *supra* note 48, at 24.

55. Walters, *supra* note 48; N.H. & M.R.C. Statement on Human Experimentation and Supplementary notes, and Appendix II thereto, *supra* note 50; PROCEEDINGS OF THE CONFERENCE ON IN VITRO FERTILIZATION: PROBLEMS AND POSSIBILITIES, Monash University Center for Human Bioethics (M.N. Brumby, ed. 1982).

56. See *infra* note 100.

57. Walters & Singer, *Conclusions and Costs* in TEST-TUBE BABIES, *supra* note 8, at 134-137; Walters, *supra* note 48, at 30.

58. Walters, *supra* note 48, at 25.

59. Leeton, Trounson, & Wood, *IVF and ET: What It is and How It Works*, in TEST-TUBE BABIES, *supra* note 8, at 2; Toulmin, *In Vitro Fertilization: Answering the Ethical Objections*, HASTINGS CENTER REP. 9 (Oct. 1978).

60. Walters, *supra* note 48, at 27, 28; Ramsey, *Manufacturing Our Offspring: Weighing the Risks*, HASTINGS CENTER REP., 7 (Oct. 1978); Toulmin, *supra* note 59, at 9, 11.

61. Carey, *Informed Consent by Participants: Who Participates? Who Consents?*, in TEST-TUBE BABIES, *supra* note 8, at 64; Walters, *supra* note 48, at 28-29.

62. Walters, *supra* note 48, at 26; N.H. & M.R.C. Statement on Human Experimentation and Supplementary Notes, *supra* note 50.

63. Walters, *supra* note 48, at 30, 31, 36, 37; Toulmin, *supra* note 59, at 11; Walters, *Cloning, Ectogenesis and Hybrids: Things to Come?* in TEST-TUBE BABIES, *supra* note 8, at 110.

64. Toulmin, *supra* note 59, at 11.

properly, still seen as experimental. The Australian NH & MRC Report of August 1982 used the following words:

While IVF and ET is an established procedure, much research remains to be done and the NH & MRC Statement on Human Experimentation should continue to apply to all work in this field In this as in other experimental fields those who conscientiously object to research projects or therapeutic programs conducted by institutions that employ them should not be obliged to participate in those projects or programs to which they object, nor should they be put at a disadvantage by their objection.⁶⁵

There is nothing surprising in this classification, for a great deal of acceptable medical activity is experimental. How otherwise can medicine advance?

A striking example is heart transplantation. The removal of a human heart and its replacement with another human heart, or with a mechanical, artificial heart is something that cannot be simulated. Failure of the operation means certain death and success means uncertain life. For this reason, such surgery is carried out only on dying patients who have given informed consent and whose defective hearts are plainly going to cause rapid death if nothing is done. The first heart transplant to a human being was attempted in 1964 in Jackson, Mississippi, with a chimpanzee's heart. It failed. The first successful heart transplant was performed in South Africa in 1967 by Dr. Christiaan Barnard. The recipient died within eighteen days. However, patients with transplanted hearts have survived for long periods from the early 1970's to the present time.⁶⁶ The first totally artificial heart was implanted in 1969 in the United States. It functioned for sixty-four hours after which a natural heart became available and was transplanted, but it failed and the patient died. His widow sued the doctors concerned claiming that the procedure followed was no more than improper experimentation. She lost her claim at the trial level and on appeal.⁶⁷ In December 1982, with prior approval of the United States Food and Drug Administration which oversees all experimental use of such devices, an artificial heart was successfully implanted in a sixty-one year old male in Salt Lake City, Utah.⁶⁸

Experimentation has characterized the development of other recent medical advances, including the treatment of coma patients by reference to the

65. N.H. & M.R.C. Statement on Human Experimentation and Supplementary Notes, Supplementary Note 4, paras. 1, 9; *see also supra* note 50.

66. NEWSWEEK, Dec. 13, 1982, at 32.

67. For a review of surgical heart transplantation and the use of artificial hearts and other artificial organs, *see* R. SCOTT, *THE BODY AS PROPERTY* 20-21, 39, 41-47, 180 (1981).

68. *Supra* note 66.

concept of brain death, the treatment of defective embryos in the womb following procedures such as amniocentesis, and transplant surgery generally.

In this article I can only summarize some of the recent international and national statements on experimentation, and suggest what may provide a practical means whereby society could oversee advanced medical work without stifling desirable initiatives. The same space constraint to which I have already referred in relation to test tube babies applies to analysis of the substantial issues raised by experimental medicine, including even the fundamental proposition that "all serious therapy is experimental."⁶⁹

Human Experimentation — International Statements

Western attitudes to medical experiments on human subjects have been substantially influenced by the Nuremberg Code. A statement of ten principles, the Code was promulgated by a war crimes tribunal in the years immediately following the Second World War, after the trial of some twenty physicians "and three others" for crimes against humanity.⁷⁰ In its judgment the tribunal said (*inter alia*): "Beginning with the outbreak of the World War II criminal medical experiments on non-German nationals, both prisoners of war and civilians, including Jews and 'asocial' persons, were carried out on a large scale in Germany and the occupied countries."⁷¹

The first rule emphasized the necessity for voluntary consent. The others prescribed conditions that should apply to all experimentation, including proper scientific qualifications in those conducting experiments, "the highest degree of care and skill," the minimization of risk, the right of a subject to discontinue participation, the elimination of any *a priori* chance of death or injury, and a humanitarian justification for undertaking the experiment in the first place.⁷²

The Nuremberg Code was neither the beginning nor the end of concern with experimental medicine. It has been written that Galen, the Greek-born physician who lived in the second century A.D. and was, after Hippocrates,

69. EXPERIMENTATION WITH HUMAN SUBJECTS (P.A. Freund, ed. 1972). This publication contains papers by twenty-one contributors who address moral, philosophical, legal, and social questions posed by human experimentation. The contributors include Margaret Mead, Hans Jonas, Henry K. Beecher, and Paul A. Freund.

70. 9 COMMONWEALTH L. BULL. 19 (No. 3, July 1983).

71. 1 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 at 181 (1941).

72. *Id.* at 181-183; C.H. WECHT, MEDICAL, LEGAL AND MORAL CONSIDERATION IN HUMAN EXPERIMENTS INVOLVING MINORS AND INCOMPETENT ADULTS (1975); Bowker, *Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code*, 19 MCGILL L. J. 161, 165 (1973); Macklin & Sherwin, *Experimenting on Human Subjects: Philosophical Perspectives*, 25 CASE W. RES. L. REV. 434 (1975).

the most distinguished physician of antiquity, "founded the experimental science of medicine."⁷³ After Nuremberg, the 18th World Medical Assembly in 1964 adopted the "Declaration of Helsinki" which was sub-titled "Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects."

The Declaration of Helsinki, which was revised by the 29th World Medical Assembly at Tokyo in 1975, draws a distinction between experiments that could be called "therapeutic" and "non-therapeutic."⁷⁴ The former have been described as any "new procedure in the prevention, diagnosis or treatment of disease." Therapeutic research or experimentation is, in this sense, medical treatment using new medical knowledge the direct purpose of which is to benefit a sick patient. Non-therapeutic research or experimentation has a wider purpose. It refers to activities and measures designed to benefit patients generally rather than the particular person who is the subject of the experiment. The testing on healthy subjects of new drugs not yet proved to be effective or safe is a good example of this kind of research.⁷⁵

With the rapid advance of medicine in recent years international statements have continued to appear; with a notable example being the *Proposed International Guidelines for Biomedical Research Involving Human Subjects* published in 1982 by the World Health Organization and the Council for International Organizations of Medical Sciences. Further, specific national attention to the issues raised by human experimentation has been seen by some countries as necessary. The United States and Australia serve as examples.

The United States

In the United States, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was established by Congress in January, 1980,⁷⁶ and concluded its operations in 1983. Its first report in December, 1981, entitled *Protecting Human Subjects*,⁷⁷ had as its subject matter, "the adequacy and uniformity of federal rules and policies, and their implementation, for the protection of human subjects in bi-

73. See Wecht, *supra* note 72.

74. Declaration of Helsinki, Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and as revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, 1 MED. J. AUST. 206-07 (Feb. 14, 1976).

75. Bowker, *supra* note 72, at 164.

76. Public Law 95-622.

77. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, PROTECTING HUMAN SUBJECTS (1981).

omedical and behavioral research.”⁷⁸ Included in the report was a comprehensive survey of all existing United States federal regulations on human experimentation, an examination of their shortcomings and a detailed analysis of five studies of misconduct by researchers and institutions in biomedical research.⁷⁹

Australia

Recent Australian Federal Government action is demonstrated by the National Health and Medical Research Council (N.H. & M.R.C.) Guidelines on human experimentation, of 1982. Published in a volume entitled *Ethics in Medical Research*,⁸⁰ the guidelines comprise a Statement of general principles to regulate all experimentation and medical research, accompanied by four sets of Supplementary Notes for special cases. One supplementary note provides a code of guidelines for IVF and ET.⁸¹ Another deals with research on children, the mentally ill, and those in “dependent relationships,” such as aged persons, wards of state, prisoners, and members of the Services. A third prescribes rules for ethics committees in hospitals and institutions where human experimentation takes place. The fourth provides a detailed framework for the conduct of “therapeutic trials” defined as “stud[ies] done in humans to find out if a treatment which it is believed may benefit a patient, actually does so.” These guidelines were first published in August 1982.⁸²

Following publication of these guidelines the Australian Federal health authorities decided to establish the national Medical Research Ethics Committee to act as a reference body for questions referred by institutional ethics committees and to maintain dialogue with Australian Federal and State Health Departments and Ministerial Standing Committees. In October, 1983, the Committee produced a further report on the use of fetal tissue entitled *Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue*.⁸³

78. *Id.*

79. *Id.*

80. NATIONAL HEALTH AND RESEARCH COUNCIL, *ETHICS IN MEDICAL RESEARCH* (1983).

81. *Id.* at Supplementary Note 4—In Vitro Fertilization and Embryo Transfer at 26-28.

82. FIRST REPORT, N.H. & M.R.C. WORKING PARTY ON ETHICS IN MEDICAL RESEARCH, (Aug. 1982). The Report was adopted subsequently by the Council at its 94th Session, October, 1982.

83. The Report was adopted by The National Health and Medical Research Council at its 96th session, October 1983, and is published in a volume entitled *ETHICS IN MEDICAL RESEARCH INVOLVING THE HUMAN FETUS AND HUMAN FETAL TISSUE*, (1983).

Achieving Regulation

These examples suggest that there is awareness in Western communities of significant issues raised by experimental medicine. Unfortunately, it is by no means clear that this awareness is general, even among scientists and medical men, or that we yet have all the procedures and sanctions needed for complete protection of the individual.

Without decrying the immense value and persuasive influence of the international declarations, it is plain that they lack "teeth." Similarly, guidelines such as those of the United States and Australia carry no sanction (other than the threat of failing to qualify for or of being deprived of government funding for research projects, and perhaps, public criticism or denunciation).⁸⁴ Yet the translation of guidelines into firm legal regulation can be difficult, because of the possibility of inhibiting desirable research, and may, at a given time, be premature.

Guidelines, criticized by some as "woolly" statements lacking precision and clarity, are frequently the only means of commencing the journey towards future legal regulation. Take for example the question of surrogate motherhood. The community is barely aware of the practice, let alone at a stage where any consensus has begun to emerge, yet there exists the clearest evidence that the practice of surrogate motherhood is under way and that it already raises extraordinarily difficult social and legal issues.

The problems for law-making are formidable. Further, experts in the course of interdisciplinary work have on occasions lifted the lid of experimental practices in institutions, and have recoiled from what they have seen:

Most Australians will react by denying that institution staff in this country abuse the residents, and by saying that this sort of thing might happen at Willowbrook in New York, or in Alabama, but not here. Sadly this is not the case Occasionally some of the more extreme examples of the dehumanization of staff and residents are reported in the papers. There are stories of medical experimentation; psychosurgery and electroconvulsive therapy being used as punishments; physical and sexual abuse of residents; exposure of patients to infectious diseases, including tuberculosis; isolation; malnutrition; children being placed in wards with violent, aggressive, or sexually abusive adults; institutional peonage; denial of medical treatment; and substandard conditions.⁸⁵

There is no shortage in other communities of examples of similar behavior.⁸⁶

84. *Supra* note 77.

85. S.C. & R. HAYES, *MENTAL RETARDATION LAW, POLICY AND ADMINISTRATION*, 151 (1982); *See also, supra* note 67, at 125-27.

86. *Supra* note 77, at Appendix E, 177-92; WECHT, *supra* note 72.

The question arises whether experimental medicine *as such* calls at present for law reform. At the risk of oversimplification I would have thought not, although particular activities can plainly call for legal regulation, for example, methods for acquiring non-regenerative human tissues, and the use of cryo-banked fertilized human eggs. For any experiment on a human subject, informed consent is essential. The laws of negligence and trespass are available and, together with traditional criminal law, capable of affording remedies against wrongdoers. Even so, a continuous matter of concern with human experimentation is the possibility of abuse—abuse of physical integrity, abuse by an expert of a position of influence over a potential subject, and abuse of power in institutional and other settings where the subject may have little or no practical prospect of obtaining a remedy or enforcing a right. The protection of human subjects in these circumstances can be peculiarly difficult but, speaking generally, may arguably be as effectively obtained from guidelines of the kind already described, from reform of administrative procedures, and from publicity, as from the creation of new legal rights. Already a great deal of protection is available under the law; but this is not to deny that special circumstances may require special legal measures.

The Council of Europe displayed an awareness of some of the major issues in its 1978 model rules on human tissue removal:

A number of experts proposed not to admit imprisoned persons as donors at all, fearing that such donations might be given in expectation of a pardon or a good conduct report enabling them to secure an early parole. The majority . . . however, preferred not to bring any exceptions for imprisoned donors If an imprisoned person gives his consent freely his wish must be respected; if, however, he is giving his consent under coercion or in order to obtain a reward against it, then his consent not being given freely, his donation cannot be accepted and no removal can take place.⁸⁷

My own opinion is that close attention should be devoted to the particular vulnerabilities of the young, the helpless, and the socially handicapped, when medical experiments, even for good reason, seek to resort to living human bodies. The need of such subjects for protection is a reflection of a state of affairs in which the unrestricted exercise by some persons of a right, a power, or a liberty can lead to the denial of rights, power, and liberty to others.

87. Council of Europe, Resolution (78) 29, Harmonization of Legislations of Member States Relating to Removal, Grafting and Transplantation of Human Substances, Explanatory Memorandum at 17.

III. LEGAL IMPLICATIONS OF BIOMEDICAL ADVANCES

Writers and commentators frequently indulge in lengthy analysis of legal problems and issues arising from the New Biology. For example, we are indebted to both Lord Devlin and Lord Justice Edmund Davies for expositions of the way in which the ancient legal principles of assault and battery still govern modern surgery.⁸⁸ A positive platoon of experts has told us in relation to AID how the classic laws of paternity will affect (or not affect, as the case may be) the child, the sperm donor, and the husband.⁸⁹ Then there are the problems of the law of wills and the Rule Against Perpetuities in relation to certain IVF children, etc.⁹⁰

In this article I have already given some attention to the impact of existing legal principles upon new biomedical "situations," but I see limited utility in this kind of analysis. A little of it can sometimes be useful in proving the inadequacy of the law. It sometimes makes good material for after-dinner speaking. But in biomedical matters the law of the past is often so plainly irrelevant that the need for reform is virtually self-evident; the status of the AID child is a perfect example. We should be giving our time and attention to reform and to the future.

Public Opinion

With biomedical subjects how much importance should be attributed to public opinion in shaping the law? While public opinion should not be the only determinant, it should, in my view, play a larger role in such matters than in some others. For example, public opinion would be of little help in framing new laws on technical aspects of conveyancing, will-making, or court procedure.

When the Australian Law Reform Commission produced its report, *Human Tissue Transplants*, in 1977 it said:

It would be difficult to imagine a reference in which the opinion of the public was more important in shaping the Commission's recommendations than this one The Commission does not suggest that its recommendations for new laws, or that laws generally, should be simple mirrors of current public will. Laws should not search for passing popularity. On occasions they may be in advance of public thinking. More often, however, laws follow, rather than precede, events. Many of the questions posed by human tis-

88. P. DEVLIN, *SAMPLES OF LAWMAKING*, 83-103 (1962); Davies, *A Legal Look at Transplants*, 62 *PROC. ROYAL SOC. OF MED.* 633 (1969).

89. See, e.g., *supra* notes 29 and 46.

90. See, e.g., Sappideen, *supra* note 46.

sue transplants are not susceptible of answer in terms of certainty, and the desirability of any particular law is not self-evident.⁹¹

In that same project the Australian Commission provided an outstanding example of the significance and measurement of public opinion in its approach to brain death. The question was whether there should be recognition by statute of the concept of death by reference to irreversible cessation of brain function. The Commission itself was satisfied, by the evidence of medical experts, scientists, philosophers, and moral theologians, that death can be properly and accurately diagnosed by such reference.

The principal concern of the Commission, however, was not with the correctness of its conclusion, but with the state of public opinion. It had received many cautions, including warnings, that the mere public mention of "brain death" would raise the spectre of body snatching, cause wide-spread community disquiet, and prompt diminution of tissue donation. Some submissions said that the law should permanently refrain from any attempt to define death at all.

The Commission first sought the views of hundreds of persons and organizations in Australia and overseas. They included governments, medical associations, churches, community groups, and universities. It conducted public hearings in every Australian capital city. It enlisted the aid of public television and radio and the press, which was generously given. Six months later the Commission was satisfied that it had reasonable knowledge of the state of Australian public opinion on brain death. It had been given the clearest indication of public acceptance. Not one witness at the public hearings expressed opposition to a legal recognition of the concept, and the written submissions were overwhelmingly in favor of it. No evidence of public anxiety was seen; and the only reservations expressed came from "a small number of medical men and lawyers."⁹²

Since completion of the Commission's Report in 1977 statutory recognition of brain death has been given by legislatures throughout Australia, as well as in other parts of the world. Of particular significance are the recommendations of the Uniformity Commissioners⁹³ and the President's Commission⁹⁴ in the United States, and the Law Reform Commission of

91. *Supra* note 13 at para. 100.

92. *Id.*, paras. 101-03.

93. The Uniform Brain Death Act, 12 UNIF. LAWS ANN. 15 (Supp. 1981), (approved in 1978 by The National Conference of Commissioners on Uniform State Laws of The United States).

94. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *DEFINING DEATH—A REPORT ON THE MEDICAL, LEGAL AND ETHICAL ISSUES IN THE DETERMINATION OF DEATH*, (1981).

Canada,⁹⁵ all of which took the same approach as the Australian Commission. The last two followed the format of the Australian legislation with its brevity and duality, stating that in determining death, regard may be had not only to the cessation of brain function but also to the more usually-encountered criteria of cessation of circulation of the blood and respiration. The model statute proposed in the United States by the President's Commission⁹⁶ has also been accepted and recommended by the American Medical Association, the American Bar Association, and the Uniformity Commissioners.⁹⁷ In New Zealand the concept of brain death had been accepted by the medical profession as early as 1972.⁹⁸

I have been discussing the significance of public opinion in circumstances where a lawmaker is satisfied that a new law or a particular reform is desirable, but is not certain of the temper of public opinion. Ascertainment that public opinion is favorable obviously brings the matter to a satisfactory conclusion. But what about the reverse case? What should a lawmaker do if shown that public opinion clearly favors a particular biomedical practice, but he or she is at the same time persuaded that there are long-term implications that could result in social disturbance, or is influenced by the strongly-held opposing views of an articulate minority? For example, both AI and IVF involve a fact that has given little concern to infertile patients and their medical advisors, or to the community at large, but which has excited fierce opposition to both practices from some moralists and theologians, as well as warnings from scientists.

The fact to which I refer is that for the first time in history, reproduction of human beings has been separated from the act of sexual intercourse between male and female. This is seen by some as representing the direct undermining of a fundamental religious principle. The scientist, on the other hand, can foresee revolutionary social changes flowing from elimination of the need for human beings to mate in order to reproduce. A prominent Australian immunologist recently expressed the opinion that the practices of artificial conception that have already developed "have a far greater significance for human civilization than the atom bomb."⁹⁹ The words of Aldous Huxley quoted at the beginning of this article thus take on added significance.

At the same time there is beginning to emerge credible evidence of public

95. Criteria for the Determination of Death, Law Ref. Comm. Canada, Rpt. No. 15 (Minister of Supply & Service, Canada, 1981).

96. *Supra* note 94, at 160.

97. *Id.*

98. Editorial, *The Moment of Death*, 75 NEW ZEALAND MED. J. 97 (1972).

99. *Supra* note 7.

approval of human artificial insemination and *in vitro* fertilization. In the past two years three Australian national public opinion surveys conducted by the Australian affiliate of Gallup International have shown high rates of public approval of both practices, in the region of 70%.¹⁰⁰ A 1983 survey of a more penetrating nature concerning AID is now in the course of evaluation and seems likely to give similar confirmation.¹⁰¹ It may well be that the medical profession, its patients, and the public are sensibly confining their attention to present practices and present problems, and do not find them disturbing. Should not reform and lawmaking on such a subject be a step-by-step progression, and not an attempt to encompass all possible future difficulties?

Should a legislator reject public opinion (assuming that it is reliably made known to him) and instead respond to his own apprehensions, or to direct external pressures? It is a difficult question but my personal answer is no. I believe that those of us who live in Western-style democracies should be influenced by that fact in relation to lawmaking. A democracy is not an autocracy, a theocracy or an aristocracy, and accordingly its laws should not be made, and legal prohibitions should not be introduced, in response to the demand of minorities and in defiance of public opinion. This is particularly the case when existing laws, made for earlier social conditions, cause injustice and highlight the need for reform. We have already seen that this has happened in the case of brain death, and with human artificial insemination.

Principle

It is possible that both credibility and acceptance of legislation will be determined to a large extent by the presence or absence of clear underlying principles. If it is obvious that the framers of the law have taken into account fundamental considerations of justice or morality, for example, the tension between the public interest in improved community health standards on the one hand and individual rights to personal autonomy on the other; or the reasonableness of an individual's claim to a particular kind of medical treatment, or to justice under the law (for example, the claim of the AID

100. See Brumby, *Australian Community Attitudes to In Vitro Fertilization*, MED. J. AUST. 650 (Dec. 10/24, 1983). This article analyzes two surveys conducted respectively in July, 1982, and April, 1983, concerning IVF, showing—*inter alia*—public approval ratings of 67% and 74%, respectively. A survey by the same organization (The Roy Morgan Research Centre Pty. Ltd.) in September, 1983, concerning AID, conducted at the request of The Advisory Committee on Human Artificial Insemination of New South Wales (of which the author, Mr. Russell Scott, is Chairman) showed public approval at 70%.

101. Survey conducted by The Advisory Committee on Human Artificial Insemination, *supra*, in 1983 under the direction of Dr. G. Rawson of the Department of Health Administration at The University of New South Wales, Sydney, Australia.

child to a clear legal status), that law should have a better prospect of survival.

Referring again to the report *Human Tissue Transplants* the Australian Law Reform Commission devoted a chapter to explanation of the principles underlying its recommendations and the basic questions which it sought to answer before drafting model legislation.¹⁰² That legislation has now been enacted with only minor variations in all Australian mainland states and territories.

Sanctions and Punishment

The prescription of penalties and sanctions in a biomedical statute can raise special consideration. First, it is possible, that a biomedical law may not need penalties at all. If its function is to prescribe orderly procedures on a subject that may be directed to securing benefits for both individuals and the public, and which does not arouse moral indignation or offend community values, it may be preferable to omit offense provisions. The English took this view with the Human Tissue Act, 1961. Much will depend on the purpose and provisions of the statute.

Secondly, if penalties are called for, the question of severity should be carefully considered. One reason is that in many Western societies a hidden sanction already applies to members of the medical professions. This arises from the fact that conviction for a criminal offense, even if the penalty is minor, will expose the practitioner to disciplinary measures, and could ultimately result in deregistration and loss of the right to practice. It may therefore be that even a small penalty could have a drastic result. Further, there is the possibility that a penalty of apparent reasonableness could result in injustice. My comment here is dictated by consideration of the Report of the Victorian Committee on Donor Gametes in August 1983.¹⁰³ A number of the recommendations of that Committee advocated that specified actions be made unlawful. These could include the acts of patients who may seek to join a hospital IVF program using donated gametes, without first undergoing a long period of medical treatment, or who may act in a way that causes confusion in relation to the genealogical origin of a child (for example, a husband and wife having sexual intercourse on the same day as the wife receives an implanted embryo). Arguably, there should be no penalty in some such cases. It will be interesting to see whether the Victorian legislation, when prepared, will impose criminal penalties upon infertile couples

102. *Supra* note 8,, at Ch. 2.

103. *Supra* note 52.

who breach the proposed statute in circumstances that would not normally be thought punishable or even liable to criticism.

The Practicability of a Statute

A final consideration for lawmakers on biomedical subjects is the necessity for a proposed statute to be practicable. Two illustrations will show the value of considering questions of practicability and common sense. The first relates to the issue of whether the law should require that comprehensive personal records be kept in relation to AID and IVF. My understanding is that comprehensive records are normally kept in relation to IVF. AID however, is a different matter. The practice of clinics destroying records of AID is well documented in both England¹⁰⁴ and Australia,¹⁰⁵ no doubt because of the possibility of drastic legal consequences befalling a donor. Reasons can be offered to support the desirability of comprehensive record keeping, including the assistance that such records can offer to the future psychological and medical welfare of the child and the donor. Reasons may also be offered for maintaining secrecy and confidentiality of at least part of the records, namely that part that would identify a sperm donor.

Assuming that a law were to be introduced requiring that personal records be kept, but providing for confidentiality of identifying information, the fact is that no entirely effective guarantee could ever be given to the persons affected that secrecy and confidentiality would be total or permanent. The least of the reasons for this is that laws can be abolished or amended. In other words, if a record is kept there must always exist a possibility that its contents will become known regardless of the safeguards.

In these circumstances, should a record-keeping law that requires secrecy and confidentiality be regarded as practicable and capable of achieving its object? I suggest that the answer to this question has to be yes. My reason is that the imperfection of such a law arising from its liability to be abolished or amended, is characteristic of all law in a sovereign state. Human institutions are not perfect.

The second illustration of the need for practicability relates to the proposi-

104. See LAW COMMISSION (ENGLAND), FAMILY LAW—ILLEGITIMACY, LAW COM. RPT. NO. 118, paras. 12.22, 12.23, (H.M.S.O. 1982).

105. Direct *viva voce* information was supplied to the Advisory Committee on Human Artificial Insemination in 1982 and 1983 by medical staffs at artificial clinics operating in New South Wales that records relating to AI are destroyed on a regular basis. See *supra* note 100; See also, Currie-Cohen, Luttrell & Shapiro, *Current Practice of Artificial Insemination by Donor in the United States*, 300 NEW ENG. J. MED. 585 (1979); Smith, *The Razor's Edge of Human Bonding: Artificial Fathers and Surrogate Mothers*, 5 W. NEW ENG. L. REV. 639, 644 (1983);

tion, which I support, that the law has no business, or mandate, to regulate all aspects of a citizen's life. There are, arguably, some areas in which the law should not become involved, particularly if they lead to interference with intimate matters where personal autonomy should prevail. A related consideration is that the law should not risk bringing itself into disrepute by purporting to proscribe behavior when the proscription has little prospect of being effective. Thus, one frequently hears in discussion of human artificial insemination, the suggestion that AID, and even AIH should be made unlawful except when done by a licensed hospital or medical practitioner. Thus, a woman self-administering AI at home, using her husband's sperm, would commit an offense.¹⁰⁶ A law to this effect has been envisaged by more than authoritarians. The Council of Europe in its 1979 draft model code on human artificial insemination provided that non-medical performance of AID should be unlawful.¹⁰⁷

My own reaction to this suggestion is to doubt the possibility of its effectiveness. Human artificial insemination is, in one sense, only a step removed from sexual intercourse. The thought of a modern law, anywhere, attempting to proscribe or regulate copulation is risible; to say the least. In our 1984, as opposed to George Orwell's, how could such a law ever be administered or policed? With artificial insemination, the likelihood, in my view, would be that such a law would receive little respect. Practicability suggests that the lawmaker could think of regulating human artificial insemination when publicly practiced—overtly or covertly—by hospitals, clinics, the medical profession, or anybody else, and should not envisage controls over the private behavior of every private citizen.

IV. CONCLUSION

Evaluation of Law, Guidelines and Monitoring Procedures

Is there a touchstone that will enable accurate evaluation of the merit of suggestions for government and community response to bioethical problems and biomedical advances? I think not. Each problem and each advance is

106. See generally, Smith, *A Close Encounter of the First Kind: Artificial Insemination and an Enlightened Judiciary*, 17 J. FAM. L. 41 (1978).

107. *Draft Recommendation on Artificial Insemination of Human Beings*, Dir. Jur. (79) 2, Arts. 2, 4. (March 5, 1979, Strasbourg).

Interestingly, the member nations of The Council of Europe did not accept the Draft Code.

In a letter to the author, Mr. Scott, dated June 21, 1984, from Mr. Ferdinando Albanese, Deputy Director of Legal Affairs of the Secretariat General of The Council of Europe, it is stated, "The Council of Europe draft Recommendation on the artificial insemination of human beings is still before the Committee of Ministers and there is no indication, for the moment, of any intention of the Committee to put this draft again on its agenda."

likely to require its own response. If the official armory of responses contains guidelines, common law, existing statutes, and new legislation, which one or more of them should be produced to resolve the issues raised by genetic counseling, artificial conception, or the permanent coma patient who still has some brain function?

Sometimes new legislation will be clearly needed, as it has been with human tissue transplantation. On other occasions the law should, at present, leave well enough alone, as is undoubtedly the case with some of the conjectured future consequences of genetic engineering and *in vitro* fertilization. Sometimes guidelines may be the best means of providing assistance, and at the same time encouraging work that could bring substantial benefit to the community. In principle I favor a monitoring approach rather than a prohibitory approach. There are great benefits to be gained for society from experimental medicine and the New Biology. At the same time there are obviously dangers and risks.

A tension arises between the urge to improve the human condition, and reactionary concern that social institutions may be weakened. It is no answer for science simply to demand unfettered freedom, or for opponents of proven procedures that are not manifestly harmful to call for blanket legal prohibition, as some have continually done with IVF. Knowledge cannot be unknown. My own preference for a general approach on the part of society and the law to biomedical advances is, first, to regard the entire field as one of national interest and not of sectional or parochial concern. Next, because the issues tend to be complex, they demand an interdisciplinary adjudication. How can doctors, lawyers, scientists, politicians, theologians, or philosophers alone resolve the issues posed by the artificial prolongation of life, or genetic manipulation?

Direction should come, ultimately, from the Parliament, which should envisage permanent monitoring of developments. The monitoring body should have the skills to formulate, and recommend when needed, guidelines, codes of practice, and legal controls. We already have the pale glimmerings of such an organization in Australia with the existence of the National Medical Research Ethics Committee and a national Law Reform Commission. One thing is clear, and we no longer need Aldous Huxley to confirm it: the problems of bioethics will not diminish. They will multiply. We need balance, courage, and compassion. We also need enlightened lawmakers.